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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Stewart Francis Ledgard

JAMES68.013APC

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Knobbe Martens Olson & Bear LLP  
2040 MAIN STREET  
FOURTEENTH FLOOR  
IRVINE, CA 92614

EXAMINER

HELM, CARALYNNE E

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

12/28/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcarter@kmob.com

eOAPilot@kmob.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/573,941	<b>Applicant(s)</b> LEDGARD, STEWART FRANCIS	
	<b>Examiner</b> CARALYNNE HELM	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 28,30 and 37-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38,39,43-47 and 53-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/23/07</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Note to Applicant: References to paragraphs in non-patent literature refer to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference)

### ***Election/Restrictions***

Applicant's election with traverse of Group II and the species where the treatment substance is a nitrification inhibitor, the route of administration is oral and the delivery vehicle is a solution in the reply filed on August 31, 2009 is acknowledged. The traversal is on the ground(s) that the purpose of the Ludden et al. is to improve animal performance instead of the claimed reduction of nitrogen loss from soil exposed to animal waste. This is not found persuasive because the intent of Ludden et al. is fundamentally the same as that of the instant claims (e.g. reduction of the loss of nitrogen from the animal to the environment). Even if, ad arguendo, Ludden et al. did not appreciate the same purpose as instant applicant, Klopfenstein et al. (see below for citation) teach that the output of nitrogen in animal waste is lost to the environment via volatilization from manure in contact with soil (e.g. feedlots) and leaches into the groundwater, contaminating the local ecosystem and producing undesirable odors (see page 1 column 2 paragraph 1-page 2 column 1 line 6). They go on to teach that decreasing the nitrogen excreted by livestock can minimize this issue (see page 2 paragraph 2). Klopfenstein et al. also teach that in beef cattle excess urea is excreted and converted into a volatile ammonium by urease (see page 10 paragraph 2). One method of reducing nitrogen excreted by livestock taught by Klopfenstein et al. is by the

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administration of specialized feed additives to the animals (see page 6 lines 10-14).

Both Klopfenstein et al. and Ludden et al. recognize deleterious consequences due to the action of urease in ruminant animals and one of ordinary skill in the art would have found it obvious to combine their teachings. Since the urease inhibitor of Ludden et al. was known to be effective at upon administration to an animal rumen, this ordinarily skill in the art would have then found it obvious to select this urease inhibitor as a specialized feed additive as taught by Klopfenstein et al. Therefore the common technical feature is not a special technical feature because prior art already appreciated the purpose of the claimed method as desirable and taught its process steps.

Claims 38-39, 43-47 and 53-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

Claims 28, 30, 37, 40, 49, and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klopfenstein et al. (Council for Agricultural Science and Technology Issue Paper 21 July 2002) in view of Swerdloff et al. (US Patent No. 4,517,004).

Klopfenstein et al. teach that the output of nitrogen in animal waste is lost to the environment via volatilization from manure in contact with soil (e.g. feedlots) (see page 1 column 2 paragraph 1-page 2 column 1 line 6; instant claim 1). Additionally, they teach that it is desirable for manure to be applied to the cropland where the animal feed originated; however, as livestock units have increased in size the plant needs of the local cropland are exceeded by the nitrogen nutrients in the manure produced by the local livestock (see page 2 column 1 paragraph 1). When manure nutrients (e.g. nitrogen) are applied to plants at a rate beyond what they need, the excess nitrogen leaches into the groundwater thereby contaminating the local ecosystem and environment (see page 2 column 1 paragraph 1). It is also taught that much of the nitrogen excreted in cattle urine is volatilized (see page 7 column 1 paragraph 3-column 2 line 2; instant claim 37). Klopfenstein et al. go on to teach that decreasing the nitrogen excreted by livestock can minimize this issue (see page 2 paragraph 2). One

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method of reducing nitrogen excreted by livestock taught by Klopfenstein et al. is by the administration of specialized feed additives to the animals (see page 6 lines 10-14; instant claims 49 and 51). While Klopfenstein et al. teach the reduction of nitrogen from soil exposed to waste from an animal by 1) identifying animals whose waste (urine or manure) is applied to soil, 2) orally introducing a treatment substance to the animals and 3) excreting waste from the animals onto the soil, they do not explicitly teach that the additive is a nitrification inhibitor.

Swerdloff et al. teach a collection of compounds that act as both urease inhibitors and nitrification inhibitors envisioned to reduce the nitrogen lost to the environment from soil (see column 1 lines 29-32 and 50-53 and column 3 line 66-column 4 line 1).

Swerdloff et al. also teach the compounds being prepared in liquid (solution) form where water is an envisioned carrier (see column 7 lines 48-50; instant claim 52). They go on to teach that in addition to agricultural applications, the compounds are envisioned for use in other applications where inhibition of urease and/or nitrification is desired (see column 8 lines 54-59). Swerdloff et al. specifically name use as a feed additive as one such application (see column 8 line 61; instant claim 40). Testing of four of the compounds demonstrated that one pair was efficacious as a urease inhibitor and of this pair that one was tested and found to also act as a nitrification inhibitor (see tables I, II, and III).

In light of the teachings of Swerdloff et al. that nitrification inhibitors can reduce nitrogen loss from soil and the administration of these inhibitors to animals as feed additives, it would have been obvious to one of ordinary skill in the art at the time of the

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invention to select a nitrification inhibitor as the feed additive in the method taught by Klopfenstein et al. Therefore claims 28, 30, 37, 40, 49, and 51-52 are obvious over Klopfenstein et al. in view of Swerdloff et al.

Claims 28, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klopfenstein et al. in view of Swerdloff et al. as applied to claims 28, 30, 37, 40, 49, and 51-52 above, and further in view of Cookson et al. (Soil Biology and Biochemistry 2002 34:1461-1465) and Davis et al. (Journal of Animal Science 1956 515-522).

Klopfenstein et al. in view of Swerdloff et al. make obvious the method of instant claims 28 and 40. This modified reference does not explicitly teach dicyandiamide as a nitrification inhibitor.

Cookson et al. teach that dicyandiamide is a nitrification inhibitor known to reduce the loss of nitrate (nitrogen) from cattle urine on soil (see page 1461 column 1 paragraph 1 and page 1464 column 1 paragraph 1).

Davis et al teach that dicyandiamide was known as a nitrogen source in animal feed (see page 515 paragraph 1). Thus one of ordinary skill in the art would have expected this compound to be suitable for oral administration to livestock.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use dicyandiamide as the feed additive since it was a nitrification inhibitor functionally equivalent to those taught by Klopfenstein et al. in view of Swerdloff et al.

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Therefore claims 28, 40, and 42 are obvious over Klopfenstein et al. in view of Swerdloff et al., Cookson et al., and Davis et al.

Claims 28 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klopfenstein et al. in view of Swerdloff et al., Cookson et al., and Davis et al. as applied to claims 28, 40, and 42 above, and in further view of Hamilton (Basic Cattle Nutrition Fact Sheet 1991).

Klopfenstein et al. in view of Swerdloff et al., Cookson et al., and Davis et al. make obvious the method of instant claim 28 where the nitrification inhibitor is dicyandiamide (DCD) that is administered orally to animals that include cattle. This modified reference is silent regarding whether the DCD is eliminated along with the animal waste.

Hamilton teaches that the rumen is the beginning of the digestive tract in ruminant animals (e.g. cattle) serving as a processing site for orally injected substances once that have passed from the mouth and through the esophagus (see page 1 paragraph 2 and figures 1 and 2). Therefore upon oral administration of DCD as taught by Klopfenstein et al. in view of Swerdloff et al., Cookson et al., and Davis et al., it would enter the rumen.

Applicant's disclosure indicates that upon rumenal administration of DCD, the compound is absorbed and excreted in the animal's waste (see instant specification page 24 lines 23-24). Since the method of Klopfenstein et al. in view of Swerdloff et al., Cookson et al., and Davis et al. also delivers DCD to the animal rumen, it must also be



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processed in the same fashion. Therefore the method of Klopfenstein et al. in view of Swerdloff et al., Cookson et al., and Davis et al. includes the excretion of the DCD in the animal waste. Thus claims 28 and 48 are obvious over Klopfenstein et al. in view of Swerdloff et al., Cookson et al., Davis et al., and Hamilton.

Claims 28, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klopfenstein et al. in view of Swerdloff et al. as applied to claims 28, 30, 37, 40, 49, and 51-52 above, and further in view of Zerulla et al. (Biology and Fertility of Soils 2001 34:79-84).

Klopfenstein et al. in view of Swerdloff et al. make obvious the method of instant claims 28 and 40. This modified reference does not explicitly teach 3,4-dimethylpyrazole phosphate as a nitrification inhibitor.

Zerulla et al. teach that 3,4-dimethylpyrazole phosphate is non-toxic nitrification inhibitor known to reduce the loss of minimize the loss of nitrate (nitrogen) soil (see page 79 and page 80 column 2 paragraph 6-page 81 column 1 paragraph 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use 3,4-dimethylpyrazole phosphate as the feed additive since it was a nitrification inhibitor functionally equivalent to those taught by Klopfenstein et al. in view of Swerdloff et al. Therefore claims 28, 40, and 41 are obvious over Klopfenstein et al. in view of Swerdloff et al. and Zerulla et al.

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Claims 28, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klopfenstein et al. in view of Swerdloff et al. as applied to claims 28, 30, 37, 40, 49, and 51-52 above, and further in view of Schaefer et al. (US Patent No. 5,505,968).

Klopfenstein et al. in view of Swerdloff et al. make obvious the method of instant claims 28 and 40. This modified reference does not explicitly teach administration of the nitrification inhibitor feed additive via drench.

Schaefer et al. teach the administration of a supplement (additive) to an animal by adding it to the food (feed supplement) or via drench.

As a known alternative (functionally equivalent means of oral delivery) to feed supplementation, it would have been obvious to one of ordinary skill in the art at the time of the invention to administer the nitrification inhibitor of Klopfenstein et al. in view of Swerdloff et al. via a drench. Therefore claims 28, 49, and 50 are obvious over Klopfenstein et al. in view of Swerdloff et al. and Schaefer et al.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/  
Examiner, Art Unit 1615

/Robert A. Wax/  
Supervisory Patent Examiner, Art Unit 1615